



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0918]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Labeling Requirements for Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0572. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Labeling Requirements for Prescription Drugs

This information collection supports FDA regulations governing the labeling of prescription drugs. The regulations are codified in 21 CFR part 201, subpart B (21 CFR 201.50 through 201.58) and set forth both general requirements, as well as specific content and format requirements. The regulations also provide for requesting a waiver from any labeling requirement and do not apply to biological products that are subject to the requirements of section 351 of the Public Health Service Act.

We are revising the information collection to include burden associated with regulations applicable to medical gas labeling found in § 201.328 (21 CFR 201.328) and established by a final rule in the *Federal Register* of November 18, 2016 (81 FR 81685 at 81694). While we included corresponding changes and adjustments resulting from the final rule to the information collection approved under OMB control number 0910-0139 as it pertains to good manufacturing practice requirements and regulations in part 211 (21 CFR part 211), we did not make corresponding changes and adjustments to this information collection with regard to burden that may be associated with labeling requirements found in § 201.328 (81 FR 81685 at 81694).

To assist respondents with the information collection we continue to develop and issue guidance documents, available from our searchable guidance database at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. All Agency guidance documents are issued consistent with our good guidance practice regulations found in 21 CFR 10.115, which provide for public comment at any time.

In the *Federal Register* of September 7, 2021 (86 FR 50134), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
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Labeling requirements for prescription drugs; §§ 201.56 and 201.57	414	1,326	549	3,349	1,838,601
Labeling of medical gas containers; § 201.328	260	1,663	432,380	0.17 (10 minutes)	73,505
Total			432,929		1,912,106

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

New drug product and biological product applicants must: (1) design and create prescription drug labeling containing “Highlights,” “Contents,” and “Full Prescribing Information”; (2) test the designed labeling (for example, to ensure that the designed labeling fits into carton-enclosed products); and (3) submit it to FDA for approval. Based on our experience with the information collection, we estimate 414 applicants will prepare an average of 549 prescription drug labels and assume it will require 3,349 hours to design, test, and submit to FDA as part of a new drug application or a biologics license application. Similarly, new medical gas containers must meet applicable requirements found in part 211, as well as specific labeling requirements in § 201.328. We estimate that 260 respondents will incur burden for the design, testing, production, and submission of labeling for new medical gas containers as required under § 201.328 and assume an average of 10 minutes (0.17) is required for these activities.

Our estimated burden for the information collection reflects an overall increase resulting from an increase in submissions for new product labeling as well as from the revision to include burden associated with requirements in § 201.328.

Dated: December 6, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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